

a protective sleeve surrounding a proximal longitudinal portion of the catheter;

a manifold connected to the protective sleeve for attachment to a hub of an artificial airway in fluid communication between the respiratory tract of [the] a patient and a ventilator, said manifold having means for accommodating inspiration and expiration of respiratory gasses; and

a valve connected to the manifold and pivotally moveable with respect thereto for engaging the distal end of the catheter to minimize the amount of air being drawn thereinto responsive to suction through the catheter wherein the valve comprises at least one protrusion on a surface of the valve.

18. (Amended) The apparatus according to Claim 16 further comprising means for enhancing turbulence of the [airflow] air.

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## Remarks

Claims 1 - 25 are presented for Examiner Erez's consideration. Pursuant to 37 C.F.R. § 1.111, reconsideration of the present application in view of the foregoing amendments and the following remarks is respectfully requested.

### Rejections under 35 U.S.C. § 112, first paragraph.

By way of the Office Action mailed June 6, 2001, Examiner Erez rejected claims 2-4, 9, and 15-21 under 35 U.S.C. § 112, first paragraph for failing to particularly point out and distinctly claim the subject matter which the Applicants regard as the invention. This rejection is respectfully **traversed** to the extent that it may apply to the presently presented claims.

It is respectfully suggested that the rejections of claim 2 should be withdrawn in view of the language contained within the specification on page 8, lines 15-18, which is reproduced below:

"As used herein, distal refers generally to the direction of the patient, while proximal refers to the direction of the clinician. Unless otherwise noted, the drawings of FIG. 2A are oriented such that the distal (patient) end is toward the top of the page, while the proximal (clinician) end is toward the bottom of the page."

This language provides support for the use of the terms "distal" and "proximal" in the claims, and it is respectfully requested that the rejections of claim 2 under 35 U.S.C. § 112, first paragraph be withdrawn.

The rejections of claims 3, 6, 9, 15 and 18 for insufficient antecedent basis have been addressed by the above amendments.

Provisional Double Patenting Rejection Over Co-Pending Application 09/460,257

By way of the Office Action mailed June 6, 2001, Examiner Erez has provisionally rejected claims 1-13 and 22-25 under the judicially created doctrine of obviousness-type double patenting over copending Application No. 09/460,257. Application No. 09/460,257 has been abandoned, and was pending in Art Unit 3761 under Examiner Teena K. Mitchell.

Obviousness-Type Double Patenting Rejection Over U.S. Patent No. 6,227,200 in view of U.S. Patent No. 6,168,758 to Forsberg et al.

By way of the Office Action mailed June 6, 2001, Examiner Mitchell has rejected claims 1-9, 11-17, and 20-25 under the judicially created doctrine of obviousness-type double patenting over U.S. Patent No. 6,227,200 in view of Forsberg et al. A terminal disclaimer will be filed to overcome this rejection.

Rejections Under 35 U.S.C. § 102(b)

By way of the Office Action mailed June 6, 2001, Examiner Erez rejected claims 1, 11 and 15 under 35 U.S.C. § 102(b) as allegedly being anticipated and thus unpatentable over U.S. Patent Number 5,490,503 to Hollister. This rejection is respectfully **traversed** to the extent that it may apply to the presently presented claims.

On page 5 of the Office Action mailed June 6, 2001, Examiner Erez stated:

"Hollister discloses an apparatus comprising a suction catheter **1** configured for removing fluids from a respiratory tract of a patient having a distal end configured for suctioning secretions from the respiratory system of a patient; a protective sleeve **2** surrounding a proximal longitudinal portion of the catheter; a manifold **4** defining a ventilation circuit disposed in communication with the catheter to be advanced through the ventilation circuit of the manifold and into the respiratory tract of the patient; and a valve **70** disposed in the manifold, the valve being configured to selectively limit the withdrawal of air from the ventilation circuit and for at least partially occluding the distal end of the catheter, the valve being able to frictionally engage the distal end (col.2, lines 1-45), wherein the valve comprises at least one protrusion **82, 84** on at least one surface of the valve."

To establish anticipation under 102(b), the cited reference must teach each and every element or step of the rejected claim. Hollister does not disclose at least one protrusion on at least

one surface of the valve. Hollister discloses a novel wiper seal and one way valve assembly 70, which is formed as an integral, one-piece molding of a resilient material, such as silicone rubber. (Hollister, col. 4, lines 14-18). Four one-way duckbill valves 82 to 85 are included in the valve assembly, and are integrally molded with the valve assembly. (Hollister, col. 4, lines 35-38). As clearly shown in Figures 2 and 4, none of the valves disclosed in Hollister have at least one protrusion on at least one surface of the valves 82 to 85.

As Hollister does not disclose at least one protrusion on at least one surface of the valve, it is respectfully submitted that claims 1, 11 and 15 are in condition for allowance, and such allowance is respectfully requested. Additionally, as dependent claims 2-10 and 22-25 depend from independent claim 1, and dependent claims 12 – 14 depend from independent claim 11, and dependent claims 16-21 depend from claim 15, these claims are also in condition for allowance.

Rejections Under 35 U.S.C. § 103(a)

In the Office Action mailed June 6, 2001, Examiner Erezco also rejected claims 2, 5, 7-10, 12, 16, and 17 under 35 U.S.C. § 103 as allegedly being obvious to one of ordinary skill in the art at the time the invention was made and thus unpatentable over U.S. Patent Number 5,490,503 to Hollister in view of U.S. Patent Number 5,582,161 to Kee. These rejections are respectfully **traversed** to the extent that they may apply to the presently presented claims.

The Examiner stated, on page 6 of the Office Action:

“Hollister discloses all the limitations of the above mentioned claims but fails to teach a valve comprising a flap movable between a first [*sic*], distal position and a second, proximal position.

Kee discloses a valve comprising a flap **20** movable between a first [*sic*] , distal position, and a second, proximal position (col. 4, lines 49-61).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to employ the valve of Kee to that of Hollister because the valve of Kee is capable of closing off the distal end of the adapter to increase the sanitary protection (col. 2, lines 6-10; col. 3, lines 54-60).”

As noted above, Hollister does not disclose a protrusion on at least one surface of the valve. A close review of the Kee reference shows that Kee does not remedy this omission in Hollister. As such, the combination of Hollister and Kee does not disclose or render obvious Applicant's invention as claimed in the presently presented claims, and allowance of these claims is respectfully requested.

Claims 5, 16, 7, 8, 17, 9, 10 and 12 are also rejected by the Examiner in numbered paragraphs 17-22 on page 7 of the office action. In view of the above, it is respectfully submitted

that all of the presently presented claims are in condition for allowance, and such allowance is respectfully requested.

For the reasons stated above, it is respectfully submitted that all of the presently presented claims are in form for allowance.

Lastly, Examiner Erez's attention is drawn to the Information Disclosure Statement which is being filed contemporaneously herewith. Examiner Erez is requested to make of record receipt and review of the documents listed therein.

Please charge any prosecutorial fees which are due to Kimberly-Clark Worldwide, Inc. deposit account number 11-0875.

The undersigned may be reached at: (770) 587-8612.

Respectfully submitted,

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CERTIFICATE OF MAILING

I, Erminia Brown, hereby certify that on November 13, 2001 this document is being deposited with the United States Postal Service as first-class mail, postage prepaid, in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231.

By: Erminia Brown  
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